



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 5, 2004
(amended August 17, 2004)

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No.: 4822-LGO, Oscar
DP Barcode: 298994

From: Tajah L. Blackburn, Ph.D., Microbiologist
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Regulatory Management Branch I
Antimicrobials Division (7510C)

Applicant: S.C. Johnson & Sons, Inc.
Racine, WI 53403-2236

Formulation From Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Lactic Acid	2.0%
<u>Other Ingredients</u>	<u>98.0%</u>
Total	100.0%

I BACKGROUND

The product, OSCAR (EPA Reg. No. 4822-LGO), is a new product. The applicant

requested to register the product as a sanitizer (non-food contact surfaces) and mildewstat for use on hard, non-porous surfaces in household, institutional, commercial, and animal care environments. The label claims that the product is a "one step" sanitizer (i.e., effective in the presence of a moderate organic soil load). Studies were conducted at ATS Labs, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package contained a letter from the applicant to EPA (dated January 9, 2004), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-35 (Data Matrix), three studies (MRID Nos. 461828-08, 461828-09, and 461828-10), Statements of No Data Confidentiality Claims for all three studies, and proposed label.

Note: The product registration is for a product named "OSCAR." All efficacy studies were performed on a product named "Oscar 1." No additional information was submitted to confirm that the two products were identical.

Note: EPA Form 8570-4 (Confidential Statement of Formula) contains Confidential Business Information. Data or information claimed by the applicant to be FIFRA confidential has not been included in this report.

Note: The data package also contained a document entitled "Compilation of EPA Data Reviews and Documents" (undated; pin-punched by EPA on January 30, 2004). This document contained various studies and memoranda regarding lactic acid, and was not relevant to evaluation of product efficacy.

II USE DIRECTIONS

This product is designed to be used for sanitizing hard, non-porous surfaces in bathrooms, such as non-wood finished cabinets, sinks, counter tops, diaper changing counters, diaper pails, doorknobs, faucets, floors, garbage cans, hand rails, light switches, showers, toilet seats, and exterior toilet surfaces, trash cans, bathtubs, urinals, vanity tops, and walls. The product may be used on hard, non-porous surfaces such as those made of chrome, enamel, fiberglass, Formica®, glazed porcelain, glazed tile, plastic, stainless steel, and synthetic marble. Directions on the proposed label provided the following information regarding the use of the product for Sanitization: Spray surface until thoroughly wet. Let stand for 1 minute. Then wipe. For heavily soiled areas, a pre-cleaning is required. For Mildewstat: Spray surface until thoroughly wet. Let stand for 5 minutes. Then wipe. Reapply as necessary.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizers (For Non-Food Contact Surfaces)

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous and non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent

serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. These Agency standards are presented in DIS/TSS-10.

There are cases where an applicant requests to make claims of effectiveness against additional microorganisms for a product that is to be used as a sanitizer for non-food contact surfaces. The DIS/TSS standards are silent on this matter. Confirmatory test standards would apply. Therefore, 2 product samples, representing 2 different batches, should be tested against each additional microorganism. Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. Furthermore, according to information provided in Section 12.3.2 of ASTM Method E1153-94, which is a test method for the efficacy of sanitizers for non-food contact surfaces, "an average of at least 7.5×10^5 organisms must have survived on the inoculated control squares for the test to be valid."

Products Controlling Microorganisms of Economic or Aesthetic Significance

Algaecides, slimicides, preservatives, deodorizers, and other products expressly claiming control of microorganisms of economic or aesthetic significance not directly related to human health do not require efficacy data. However, adequate dosage recommendations and complete directions for use must be provided in labeling. These Agency standards are presented in DIS/TSS-16.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant, "one-step" sanitizer, or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 461828-08 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)" for Oscar 1, by Sally Nada. Study conducted at ATS LABS. Study completion date – January 7, 2004.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three lots (Lot Nos. 472D1, 472D2, and 472D4; manufacture dates not provided) of the product, Oscar 1, were tested according to the Efficacy Data Requirements Sanitizer Test (DIS/TSS-10). ASTM Method E1153 and the AOAC Germicidal Spray Products as Disinfectants Method were referenced. The product was received ready-to-use. Each of five sterile glass carriers per lot of product was inoculated with 0.01 mL of a 48±4 hour culture of either *Staphylococcus aureus* or *Klebsiella pneumoniae* containing 5% fetal bovine serum. The inoculum was spread to within 1/8 inch of the edges of the carriers. Carriers were dried for 20-40 minutes at 35-37°C at a relative humidity of 41.3%. Carriers were returned to room

temperature and sprayed with the product (3-5 pumps) at a distance of 6-8 inches until the carrier surfaces were thoroughly wet. All carriers were held for a 1-minute exposure period. Each carrier was then placed into a jar containing 20 mL of D/E Neutralizing Broth; the jars were vigorously rotated approximately 50 rotations to suspend the surviving organisms in the neutralizer solution. After 30 minutes of neutralization, the neutralized solution was serially diluted and plated onto Tryptic Soy agar with 5% sheep blood. The plates were incubated at 35-37°C for 48±4 hours, and the colonies were counted. Controls included those for carrier quantitation, neutralization confirmation, purity, sterility, inoculum count, and viability.

Note: Per message left by Alex Hawkins of S.C. Johnson, lot 472D1 is the aged product. Supporting documentation requested.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

2. MRID 461828-09 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)" for Oscar 1, by David Rottjakob. Study conducted at ATS LABS. Study completion date – January 6, 2004.

This study was conducted against *Escherichia coli* (ATCC 11229) and *Enterococcus faecalis* Vancomycin Resistant (ATCC 51575). Two lots (Lot Nos. 472D1 and 472D2) of the product, Oscar 1, were tested using the Efficacy Data Requirements Sanitizer Test (DIS/TSS-10). ASTM Method E1153 and the AOAC Germicidal Spray Products as Disinfectants Method were referenced. The product was received ready-to-use. Each of five sterile glass carriers per lot of product was inoculated with 0.01 mL of a 48±4 hour culture of either *Escherichia coli* or *Enterococcus faecalis* Vancomycin Resistant containing 5% fetal bovine serum. The inoculum was spread to within 1/8 inch of the edges of the carriers. Carriers were dried for 20-40 minutes at 35-37°C at a relative humidity of 40.0%. Carriers were returned to room temperature, and sprayed with the product (4 pumps) at a distance of 6-8 inches until the carrier surfaces were thoroughly wet. All carriers were held for a 1-minute exposure period. Each carrier was then placed into a jar containing 20 mL of D/E Neutralizing Broth; the jars were vigorously rotated approximately 50 rotations. After 30 minutes of neutralization, the neutralized solution was serially diluted and plated onto Tryptic Soy agar with 5% sheep blood. The plates were incubated at 35-37°C for 48±4 hours, and the colonies were counted. Controls included those for carrier quantitation, neutralization confirmation, purity, sterility, inoculum count, and viability.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

Note: Antibiotic resistance of *Enterococcus faecalis* Vancomycin Resistant was verified on a representative culture. The laboratory performed a Kirby Bauer Susceptibility assay. *Staphylococcus aureus* (ATCC 25923) was the control organism. The measured zone of inhibition confirmed antibiotic resistance of *Enterococcus faecalis* Vancomycin Resistant to vancomycin. See Attachment I of the laboratory report.

3. MRID 461828-10 "EPA Hard Surface Mildew-Fungistatic Test" for Oscar 1, by Sally Nada. Study conducted at ATS LABS. Study completion date – January 6, 2004.

This study was conducted against *Aspergillus niger* (ATCC 16404). Two lots (Lot Nos. 472 D1 and 472 D2) of the product, Oscar 1, were tested using the Hard Surface Mildew Fungistatic Test Method. The product was received ready-to-use. A conidial suspension of a 7-10 day old culture containing 5% fetal bovine serum was used. Sterile 1 x 1" glazed ceramic tiles (10 per treatment) were sprayed (4 pumps) with the product from a distance of 6-8 inches until the carrier surfaces were thoroughly wet. After 5 minutes, excess liquid was allowed to drain off and the tiles were dried for 120 minutes at 35-37°C. Untreated carriers were also held for 120 minutes at 25-37°C. Following the drying period, the surfaces of each test tile and each control tile were sprayed with the conidial suspension using a DeVilbiss #152 atomizer. The tiles were returned to 35-37°C and dried for 75 minutes. Each tile (treated side up) was placed in an individual Petri dish containing hardened sterile water agar. The plates were incubated at 25-30°C for 7 days at a minimum of 95% relative humidity. The tiles were examined for growth after 7 days of incubation. If no growth was visually observed, a magnified examination was performed. Controls included those for purity and sterility.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

V RESULTS

MRID Number	Organism	Lot No.	Survivors per Carrier	Control Carrier Counts	Percent Reduction
			Geometric Mean (CFU/carrier)		
461828-08	<i>Staphylococcus aureus</i>	472D1	<200	6.03 x 10 ⁷	>99.9
		472D2	<288		>99.9
		472D4	<200		>99.9
	<i>Klebsiella pneumoniae</i>	472D1	<200	1.1 x 10 ⁷	>99.9
		472D2	<200		>99.9
		472D4	<200		>99.9
461828-09	<i>Escherichia coli</i>	472D1	<20.0	2.45 x 10 ⁶	>99.9
		472D2	<20.0		>99.9
	<i>Enterococcus faecalis</i> Vancomycin Resistant	472D1	1.17 x 10 ⁵	2.04 x 10 ⁶	94.3
		472D2	5.25 x 10 ⁴		97.4

MRID	Organism	% Growth		
		Lot No. 472 D1	Lot No. 472 D2	Control Tiles
461828-10	<i>Aspergillus niger</i>	no growth	no growth	90
		no growth	no growth	70
		no growth	no growth	80
		no growth	no growth	90
		no growth	no growth	90
		no growth	no growth	90
		no growth	no growth	70
		no growth	no growth	70
		no growth	no growth	60
		no growth	no growth	70

VI CONCLUSIONS

1. The submitted efficacy data (MRID No. 461828-08) support the use of the product, Oscar 1, as a sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae* on hard, non-porous, non-food contact surfaces in the presence of a 5% organic soil load for a contact time of 1 minute. Results showed a bacterial reduction of at least 99.9 percent of the parallel control within less than 5 minutes. Neutralization confirmation testing met the acceptance criterion; neutralizer toxicity was not evident with any of the species tested. The viability controls were positive for growth. The purity controls were reported as pure. The sterility controls did not show growth. The applicant demonstrated that at least one of the product lots (472D-1) tested was at least 60 days old at the time of testing.

Note: An unsuccessful attempt was made to contact S.C. Johnson (date May 5, 2004), to determine which lot was the aged product. A voice mail message was left requesting the missing information. I spoke with Alex Hawkins on Monday, May 10, 2004, at which time he informed me that the aged product lot was 472D-1. Supporting documentation was requested and received.

2. The submitted efficacy data (MRID No. 461828-09) support the use of the product, Oscar 1, as a sanitizer against *Escherichia coli* on hard, non-porous, non-food contact surfaces in the presence of a 5% organic soil load for a contact time of 1 minute. Results showed a bacterial reduction of at least 99.9 percent of the parallel control within less than 5 minutes. An average of at least 7.5×10^5 organisms survived on the inoculated control tiles. Neutralization confirmation testing met the acceptance criterion; neutralizer toxicity was not evident. The viability controls were positive for growth. The purity controls were reported as pure. The

sterility controls did not show growth.

3. The submitted efficacy data (MRID No. 461828-09) do not support the use of the product, Oscar 1, as a sanitizer against *Enterococcus faecalis* Vancomycin Resistant on hard, non-porous, non-food contact surfaces in the presence of a 5% organic soil load for a contact time of 1 minute. The product failed to achieve 99.9% reduction of the organism tested.

4. The submitted efficacy data (MRID No. 461828-10) support the use of the product, Oscar 1, as a fungistat against *Aspergillus niger* on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 5 minutes. No growth was observed 7 days after treatment. Testing was conducted on 2 product lots. Untreated control tiles exhibited growth of *Aspergillus niger* on 60% to 90% of the untreated tile surface. The culture purity control was pure; and the sterility controls showed no growth.

VII RECOMMENDATIONS

The following study-specific recommendations assume that the Agency is able to confirm with certainty that the tested product, Oscar 1, is the product, OSCAR, which is the subject of this efficacy report. The applicant may need to provide this information.

A. Recommendations Regarding Efficacy Claims

1. The proposed label claims that the product, OSCAR, is an effective "one-step" sanitizer against *Staphylococcus aureus*, *Klebsiella pneumoniae*, and *Escherichia coli* when used at a contact time of 1 minute. This claim is supported by the applicant's data. Upon initial review of the data package, there was no identification of the aged product lot. Alex Hawkins submitted a fax to the Agency identifying the aged product.

2. The proposed label claims that the product, OSCAR, is an effective mildewstat when used at a contact time of 5 minutes. This claim is supported by the applicant's data. Directions for use are clear, and fungistatic activity was evident from the study results.

B. Miscellaneous Recommendations

1. The following marketing claims should be removed from the product label because they heighten efficacy of the product as compared to another product: "better," "improved," "quickly [sanitizes]," "quick [way to sanitize]," and "powerized." The claim "new" may only be used on the label for a period of 6 months following approval of the label.

2. The proposed label indicates that the product may be used on fiberglass surfaces [see pages 2 and 4 of the proposed label]. Fiberglass is a porous surface. The applicant must delete this general reference to fiberglass. The applicant may indicate on the product label that the product may be used on specific fiberglass surfaces (e.g., fiberglass bathtubs).

3. The product label includes a list of surfaces [see pages 4 and 5 of the proposed label.] The introductory sentence states that the product is recommended for use on "bathroom surfaces (such as)" The applicant should revise this statement to state that the product is

recommended for use on "hard, non-porous bathroom surfaces (such as)"

4. The proposed label depicts five sets of "icons" that may be used in connection with certain fragrance names [see page 7 of the proposed label]. These "icons" include a kiwi and four other fruits (most likely an orange, lime, lemon, and grapefruit). Label descriptions of the product fragrance include "citrus," "lemon," "orange," "floral," "refreshing," "pleasant," and "clean." "Kiwi" is not named as a fragrance, is not a citrus fruit, and should not be depicted graphically on the label.

In addition, there are concerns that the fruit graphics on the label might make the product more attractive to children and thus increase the potential for accidental ingestion or other exposure. EPA has indicated that it would review the use of food and food-like fragrances in products (other than insect repellants) on a case-by-case basis. [See letter from Mr. Frank T. Sanders (Director of Antimicrobials Division) to Consumer Specialty Products Association, November 13, 2002 (see <http://www.epa.gov/oppad001/fruitgraphic.htm>)]. EPA may want to review the Application for Pesticide for the product, OSCAR, and determine whether the product will be packaged in child resistant packaging.

5. The applicant may want to make the following changes to the proposed label:

- (1) On page 2, change "or you money back" to read "or your money back."
- (2) On page 2 (in two locations), correct the spelling of "Klebsiella pneumoniae" to read "Klebsiella pneumoniae."